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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/657,353

09/08/2003

Michael R.S. Hill

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7590

08/21/2006

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EXAMINER

OROPEZA, FRANCES P

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 10/657,353	Applicant(s) MICHAEL R.S.HILL	
	Examiner Frances P. Oropeza	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 5/30/06 (Election).
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/24/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/ Restriction*

1. In the response to the restriction, claims 11-20 have been cancelled. An election of invention I., claims 1-10, was made **without** traverse in the reply filed on 5/30/06.

### *Double Patenting*

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 2 and 7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17 and 19 of U.S. Patent No. 6449507. Although the conflicting claims are not identical, they are not patentably distinct from each other because delivering at least one drug during the medical procedure is read as delivering a first vasoactive substance and delivering a second vasoactive substance.

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4. Claim 1, 2, 8 and 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 20 and 28 of U.S. Patent No. 6718208.

Although the conflicting claims are not identical, they are not patentably distinct from each other because delivering at least one drug during the medical procedure is read as delivering a first vasoactive substance and delivering a second vasoactive substance.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-4 and 6-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Duhaylongsod (US 6414018). Duhaylongsod teaches a method of performing a medical procedure comprising stimulating a vagal nerve to adjust to a first condition (asystole), delivering a first vasoactive substance (a beta-blocker, a cholinergic agent, nitroglycerine), performing a procedure (a coronary procedure/ coronary bypass procedure), and delivering a second vasoactive substance (a beta-blocker, a cholinergic agent, nitroglycerine, atropine) OR stimulating the heart to attain a second condition (using an electrical pacing system), and delivering a second vasoactive substance (a beta-blocker, a cholinergic agent, nitroglycerine, atropine) (abstract; col. 5 @ 27-46; col. 6 @ 44-50; col. 7 @ 24-34; col. 11 @ 13-35;

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col. 12 @ 18-24; col. 13 @ 32-39; col. 16 @ 38-43; col. 18 @ 10-12).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod (US 6414018) in view of Maroko (US 5153178). As discussed in paragraph 6 of this action, Duhaylongsod discloses the claimed invention except for the second substance being a vasoconstrictor, specifically epinephrine.

Marok teaches improving circulation performance using the vasoconstrictor epinephrine for the purpose of increasing the contractibility of the mammalian heart. It would have been

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obvious to one having ordinary skill in the art at the time of the invention to have used the vasoconstrictor epinephrine in the Duhaylongsod system in order to provide an alternate means to controls the heart using a pharmacological agent that improves cardiac performance (abstract; col. 1 @ 19-30; col. 23 @ 13-29; col. 34 @ 33-41).

### *Specification*

9. The specification is objected to because reference numeral "500 is not found in figure 3 and noted on page 21, line 23 of the specification.

10. The priority claimed in the specification, first paragraph, is not consistent with the information on the biographical data sheet. Update of the biographical data sheet is required.

### *Information Disclosure Statement*

11. The information disclosure statement filed 7/24/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The information disclosure sheet has been placed in the application file with the references reviewed and initialed but four foreign references (AU 9890156, AU 779255, MX 2043, WO 99/63926) lined through because no copy of the reference was supplied, three foreign references (JP 105337, JP 1181947, DE 2811325) lined through because they were not in the English language, and four non-patent literature references (Hageman et al., PACE, Subramanian, Taylor) lined through or partially lined through because



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no copy of the reference was supplied; the references (AU 9890156, AU 779255, MX 2043, WO 99/63926, JP 105337, JP 1181947, DE 2811325, Hageman et al., PACE, Subramanian, Taylor ) have not been or parts have not been considered. (See Paragraph Below)

12. The information disclosure statement filed 7/24/06 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. The information disclosure sheet has been placed in the application file with the references reviewed and initialed but two foreign references (CA 2376903, EP 1051168) lined through and three non-patent literature references (Hammond et al., Urthaler and Wilder et al.) lined through; the five references (CA 2376903, EP 1051168, Hammond et al., Urthaler and Wilder et al.) have not been considered. (See Paragraph Above)

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3766

*FO*  
*8-18-06*

  
Robert E. Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766